DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Pan Medical Ltd.
Ms. Jennie Budding
Director of R & D / Production
Barnett Way, Barnwood
Gloucester
Gloucestershire, GL4 3RT
United Kingdom

March 6, 2015

Re: K150322
Trade/Device Name: InterV Kyphoplasty Catheter and InterV Kyphoplasty Catheter (Mini)
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: February 6, 2015
Received: February 9, 2015

Dear Ms. Budding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150322

Device Name: InterV Kyphoplasty Catheter and InterV Kyphoplasty Catheter (Mini)

Indications for Use:

InterV Kyphoplasty Catheter is intended to be used for reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethymethacrylate (PMMA) bone cements).

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Special [510(k)] Summary

SUBMITTER INFORMATION

Manufacturer's Name:	Pan Medical Ltd
Manufacturer's Address:	Barnett Way, Barnwood, Gloucester, GL4 3RT UK
Telephone (DDI):	+44 1452 621621
Fax:	+44 1452 372140
Establishment Registration:	3005146147
Contact Person:	Jennie Budding (Director of R&D/Production)
Date Prepared:	06-Febraury-2015

DEVICE INFORMATION

Trade Name:	InterV Kyphoplasty Catheter & InterV Kyphoplasty Catheter (Mini)
Common Name:	Inflatable Bone Tamp
Device Class:	II
Classification Name:	Polymethylmethacrylate (PMMA) Bone Cement Arthroscope
Classification Panel:	Orthopedic Devices
Classification Regulation:	21 CFR 888.3027 21 CFR 888.1100
Product Code(s):	NDN HRX
Identification of the unmodified legally marketed device:	InterV Kyphoplasty Catheter cleared under 510(k) Number K132620
Device Description:	Both the unmodified predicate and the subject modified InterV Kyphoplasty Catheter are designed for use in balloon kyphoplasty; they come as a single-use double lumen catheter with a low profile balloon mounted on the distal tip. The balloon is designed to compress cancellous bone and/or move cortical bone as it inflates. The key components are the balloon, shaft, Y-connector and two radiopaque marker bands positioned on the inner tubing/lumen at the proximal and distal ends of the inflatable component.

Intended use:

Both the unmodified predicate and the subject modified InterV Kyphoplasty Catheter are intended to be used for reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethymethacrylate (PMMA) bone cements).

SUMMARY COMPARISON OF TECHNICAL ATTRIBUTES OF THE MODIFIED INTERV KYPHOPLASTY CATHETER TO ITS LEGALLY MARKETED PREDICATE (K132620)

TECHNOLOGICAL CHARACTERISTICS	INTERV KYPHOPLASTY CATHETER CLEARED UNDER K132620; MANUFACTURED BY PAN MEDICAL LTD.; INTV-10, INTV-15 AND INTV-20	PROPOSED MODIFIED INTERV KYPHOPLASTY CATHETER; MANUFACTURED BY PAN MEDICAL LTD.; INTV-10, INTV-15; INTV-20; INTVMN-10, INTVMN-15 AND INTVMN-20
Balloon Length (Deflated)	10, 15 and 20 mm	10, 15 and 20 mm
Maximum Recommended Inflation Volume	10 mm balloon: 4 ml 15 mm balloon:4 ml 20 mm balloon: 6 ml	10 mm balloon: 4 ml 15 mm balloon:4 ml 20 mm balloon: 6 ml
Maximum Recommended Inflation Pressure	27 ATM (400 psi)	50 ATM (750 psi)
Shaft Diameter	8 Fr	8 Fr & 6 Fr
Compatible Cannula Size	4.2 mm	4.2 mm & 3 mm
Overall Length of the Catheter	30 cm	30 cm
Effective Length of the Catheter	22 cm	22 cm
Balloon Shape	Cylindrical	Cylindrical
Balloon Material	Polyurethane	Polyurethane
Guide wire (Stylet) Material	Stainless Steel	Stainless Steel
Balloon Inflation Medium	60% Contrast	60% Contrast
Sterility	Delivered sterile (EtO)	Delivered sterile (EtO)
Shelf Life	3 years from the date of Sterilization	3 years from the date of Sterilization

ACCESSORIES KIT

Bone access tools (Bone access needle, Kirschner wire, Bone access drill, Curette, Bone access cannula); Cement delivery tools (Cement delivery cannula, Cement dispenser) and Inflation device

SUMMARY OF NON-CLINICAL TESTS

Verification activities including mechanical and functional testing as required by the risk analysis for the modifications were performed to confirm that the subject device functions as intended and does not raise any new issues of safety or effectiveness. The results from the testing demonstrated that the predetermined acceptance criteria were met and the device does not raise any new issues of safety or effectiveness.

SUMMARY OF CLINICAL TESTS

N/A- No clinical tests were conducted for this submission

CONCLUSION

As the predicate and the subject modified InterV Kyphoplasty Catheter

- have the same indications for use,
- incorporate the same materials,
- use the same operating principle,
- have the same shelf life and
- are packaged and sterilised using the same materials and processes

And based on the results from risk analysis associated verification testing, we believe that the subject modified InterV Kyphoplasty Catheter is substantially equivalent to the currently marketed predicate InterV Kyphoplasty Catheter.